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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,474	01/05/2006	Erik Rytter Ottosen	3893-0220PUS2	1370

2292 7590 08/07/2009
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EXAMINER	
KOSACK, JOSEPH R	

ART UNIT	PAPER NUMBER
1626	

NOTIFICATION DATE	DELIVERY MODE
08/07/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/563,474	OTTOSEN ET AL.	
	Examiner	Art Unit	
	Joseph R. Kosack	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49,50,63-71,77-81,83,88,89,91 and 92* is/are pending in the application.

4a) Of the above claim(s) *83,88,89 and 92* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49,50,63-71,77-81 and 91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 49, 50, 63-71, 77-81, 83, 88, 89, 91, and 92 are pending in the instant application.

Amendments

The amendment file don April 27, 2009 has been acknowledged and has been entered into the instant application file.

Previous Claim Rejections - 35 USC § 103

Claims 49, 63-65, 67, 69-71, 77, 78, 81, and 91 were previously rejected under 35 U.S.C. 103(a) as being unpatentable over Ottosen et al. (WO 2001/05744) in view of Patani et al. (*Chem Rev, 1996,* 3147-3176).

The Applicant's arguments and amendments have been considered, and have been found to be persuasive. The rejection is withdrawn.

Previous Double Patenting Rejections

Claims 49, 50, 56, 58, 63-71, 77-81 and 91 were previously rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,541,670.

The Applicant's arguments and amendments have been found to be persuasive, and the rejection is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49, 50, 63-71, 77-81 and 91 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for solvates in the solid form. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims listed above are drawn not only to the compounds themselves, but also to solvates thereof. The current skill in the art is that the existence and physical properties of solid form solvates is unpredictable. See Hildesheim et al., USPN 7,056,942, column 2, line 66 through column 3, line 5. Additionally, there are no examples present within the specification that teach a solid form solvate. The term solvate as defined encompasses solid form solvates only (page 12 of the specification.) Therefore, on the virtue of the evidence above, it would require undue experimentation for one of skill in the art to make the solid solvates that are claimed instantly.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

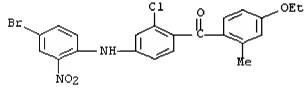
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 49, 63-65, 67, 69-71, 77, 78, 81, and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ottosen et al. (WO 2001/05744) in view of Revesz (WO 2002/76447)

Determination of the scope and content of the prior art (MPEP §2141.01)

Ottosen et al. teaches a compound of the formula



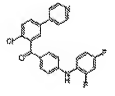
which corresponds to Formula I where R1 is methyl, R2 is chlro, there are two R3s and they are nitro and bromo, R4 is hydrogen, R5 is hydrogen, R6 is Y2-R9, Y2 is O, R9 is methyl substituted by 1 R7, and R7 is methyl. See Example 9, page 23.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Ottosen et al. does not teach where R3 and R4 is fluorine where R3 is meta to R4 and para to the NH group.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Revesz teaches various TNF alpha and IL1 beta inhibitors that have the desired three phenyl ring structure and the motif of the R3 and R4 groups such as



. See Example 3, page 14.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to synthesize the compound of Ottosen et al. and modify the R3 and R4 groups with the fluorine atoms of Revesz with a reasonable expectation of success. The motivation to make the claimed invention from the teachings of the prior art is provided by Revesz as Revesz teaches that the 2,4-difluorophenyl group is the especially preferred embodiment. See page 3, lines 13-14.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

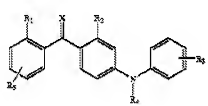
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 49, 50, 63-71, 77-81 and 91 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,541,670 in view of Revesz (WO 2002/76447). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same art specific subject matter.

Determination of the scope and content of the prior art (MPEP §2141.01)

'670 teaches a genus of compounds of the formula



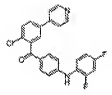
which overlaps with the instant claims where R4 is hydrogen, 1 or more R3 groups are fluorine with one at the 2-position, R5 can be amide, and all other substituents are as defined.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

'670 does not teach specifically in the claims where R3 and R4 is fluorine where R3 is meta to R4 and para to the NH group.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Revesz teaches various TNF alpha and IL1 beta inhibitors that have the desired three phenyl ring structure and the motif of the R3 and R4 groups such as



. See Example 3, page 14.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to synthesize the compound of '670 and modify the R3 and R4 groups with the fluorine atoms of Revesz with a reasonable expectation of success. The motivation to make the claimed invention from the teachings of the prior art is provided by Revesz as Revesz teaches that the 2,4-difluorophenyl group is the especially preferred embodiment. See page 3, lines 13-14.

Conclusion

Claims 49, 50, 63-71, 77-81 and 91 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph R. Kosack whose telephone number is (571)272-5575. The examiner can normally be reached on M-Th 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joseph R Kosack/
Examiner, Art Unit 1626